

DETAILED ACTION

Reassignment of Application

Please note that this application has been reassigned to Examiner Ibrahim Bori, in Art Unit 1629. In order to expedite accurate processing of the application papers, all future correspondence with the office should reflect this change.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 13, 2007, and March 23, 2009, have been considered by the Examiner. The submission is in compliance with the provisions of 37 CFR § 1.97. Enclosed with this Office Action is a return-copy of the Form PTO-1449 with the Examiner's initials and signature indicating those references that have been considered.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2010, has been entered.

Status of the Application and Claims

This Application is a 371 of PCT/IB05/00100, filed on January 17, 2005, which claims priority to US Provisional Application No. 60/540,897, filed on January 30, 2004.

Acknowledgement is made of the Applicants' Amendment and Response filed on September 22, 2010, which have been fully considered and entered.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the Instant Application.

Claims 11, 13-16, 19, 28 and 29 were previously pending. Applicants have amended claim 11. Applicants have cancelled claim 14. Therefore, claims 11, 13, 15-16, 19, 28 and 29 are currently pending and are under consideration in this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16 and 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 16 are indefinite because claims 15 and 16 depend from cancelled claimed 14. One of ordinary skill in the art would not be apprised of the meets and bounds of these claims. Claim 19 depends from claim 16.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite for reciting the phrase “a compound of Formula 1a” because “a compound of Formula 1a” is not disclosed by the claim 28. One of ordinary skill in the art would not be apprised of the meets and bounds of the claim.

Claim Rejections - 35 USC § 103-Withdrawn

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 11, 13, 15-16, 19, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Giles-Komar et al. U.S. Patent No. 7,163,681 B2 and Pfizer Products Inc. WO 03/009848 A1 (IDS dated 3/13/07) and further in view of Ono et al. Eur. J. Pharm. Sci. 1999 (U), is withdrawn for the reasons presented by the Applicants.

Allowable Subject Matter

Claims 11, 13 and 29 are allowed.

The following is an examiner's statement of reasons for allowance: A parenteral pharmaceutical composition comprising the elements of base claim 11, is not suggested or disclosed in the prior art of record. There are no other references of record that meet the requirements.

Conclusions

Claims 11, 13 and 29 are allowable.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*,

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clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IBRAHIM D. BORI whose telephone number is (571)270-7020. The examiner can normally be reached on Monday through Friday 8:00AM-5:00PM(EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY S. LUNDGREN can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/IBRAHIM D BORI/

Examiner, Art Unit 1629

/Jeffrey S. Lundgren/

Supervisory Patent Examiner, Art Unit 1629